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**IMPORTANT**

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**FACSIMILE COVER LETTER**

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From: HARVEY B. JACOBSON, JR.Date: September 22, 2000To: EXAMINER ALICIA BERMAN703/308-7922  
Facsimile Telephone NumberRe: U.S. Serial No. 09/605,054TOTAL NUMBER OF PAGES, INCLUDING COVER LETTER: 5SPECIAL COMMENTS OR INSTRUCTIONS:

Dear Ms. Berman:

As requested, attached is a copy of the Office Action issued in connection with U.S. Serial No. 09/125,810, the parent case for the above application, which indicates the allowed claims, together with copies of the allowed claims.

Respectfully submitted,

*Harvey B. Jacobson*  
HARVEY B. JACOBSON, JR. for  
JACOBSON PRICE HOLMAN & STERN, PLLC

HBJ/lhs  
Attachments

THIS COMMUNICATION IS INTENDED ONLY FOR THE USE OF THE ADDRESSEE AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED AND CONFIDENTIAL. IF YOU ARE NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE FOR DELIVERING THIS COMMUNICATION TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, COPYING, OR OTHER USE OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE. THANK YOU.

**Notice of Allowability**

Application No.

09/125,810

Examiner

Alycia Berman

Applicant(s)

CHARIOT et al.

Art Unit

1615

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

1. ☒ This communication is responsive to 24 April 2000.
2. ☒ The allowed claim(s) is/are 24-28.
3. ☐ The drawings filed on \_\_\_\_\_ are acceptable.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☒ a) ☒ All b) ☐ Some c) ☐ None of the CERTIFIED copies of the priority documents have been  
 1. ☒ received.  
 2. ☐ received in Application No. (Series Code / Serial Number). \_\_\_\_\_  
 3. ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* Certified copies not received: \_\_\_\_\_
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. & 119(e).

A SHORTENED STATUTORY PERIOD FOR REPLY to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office Action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be available under the provisions of 37 CFR 1.136(a).

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☐ Applicant MUST submit NEW FORMAL DRAWINGS  
 (a) ☐ because the originally filed drawings were declared by applicant to be informal.  
 (b) ☐ Including changes required by the Notice of Draftsperson's Patent Drawing Review( PTO-848) attached  
 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.  
 (c) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.  
 (d) ☐ including changes required by the attached Examiner's Amendment / Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

**Attachment(s)**

- 1 ☐ Notice of References Cited (PTO-892)  
 3 ☒ Notice of Draftsperson's Patent Drawing Review (PTO-848)  
 5 ☐ Information Disclosure Statements (PTO-1449), Paper No. \_\_\_\_\_.  
 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 2 ☐ Notice of Informal Patent Application (PTO-152)  
 4 ☐ Interview Summary (PTO-413), Paper No. \_\_\_\_\_.  
 6 ☐ Examiner's Amendment/Comment  
 8 ☐ Examiner's Statement of Reasons for Allowance  
 9 ☐ Other

THURMAN K. PAGE  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 2800

22. Coated sustained release tablet, consisting essentially of mizolastine, a fatty matrix, an organic acid, and a coating, the coated tablet having a dissolution profile which is pH independent.

23. Coated sustained release tablet, consisting essentially of mizolastine, a fatty matrix, an organic acid, and a coating, the coated tablet having a dissolution profile which is pH independent, the organic acid being selected from the group consisting of maleic, tartaric, malic, fumaric, lactic, citric, adipic and succinic acid in the form of a racemate or an isomer.

24. Coated sustained release tablet, consisting essentially of mizolastine, a fatty matrix, an organic acid, and a coating, the coated tablet having a dissolution profile which is pH independent, the fatty matrix being selected from the group consisting of hydrogenated castor oil, a hydrogenated lecithin, a long-chain fatty acid and a triglyceride esterified with one, two or three medium-chain fatty acids, the organic acid being selected from the group consisting of maleic, tartaric, malic, fumaric, lactic, citric, adipic and succinic acid in the form of a racemate or an isomer.--

#### R E M A R K S

Based on a telephone conference with the Examiner on October 1, 1999, it is believed that at least new independent claim 24 is allowable. However, since applicants believe that broader claims, as well as claims of varying scope, are allowable, applicants have taken this opportunity to amend claim 8 and also add new independent claims 21-23. Claim 8, as amended, clearly distinguishes over an enteric coating. New independent claim 21 limits the tablet to one "consisting essentially of". New

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Maryvonne CHARLOT et al

Group Art Unit 1615

Serial No. 09/125,810

Examiner Berman

Filed: August 26, 1998

For: SLOW-RELEASE PHARMACEUTICAL  
FORMULATIONS CONTAINING MIZOLASTINEAMENDMENT AFTER FINAL REJECTION

BOX AF

Asst. Commissioner of Patents

Washington, D.C. 20231

EXPEDITED PROCEDURE

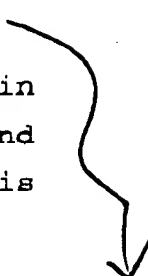
Sir:

In response to the Office Action mailed December 8, 1999  
(Paper No. 12), please amend the above-identified application as  
follows:

IN THE CLAIMS:

Cancel claims 1-23 without prejudice or disclaimer and  
add the following new claims:

-- 25. Coated sustained release tablet of claim 24, wherein  
the tablet contains 0.5% to 12% by weight of the mizolastine and  
the weight ratio between the mizolastine and the organic acid is  
between 0.3 and 1.



26. Coated sustained release tablet of claim 25, wherein the tablet further contains excipients selected from the group consisting of lactose, mannitol, microcrystalline cellulose, starch, calcium phosphate, calcium sulphate, polyvidone, hydroxypropyl-cellulose, hydroxypropylmethylcellulose and methylcellulose.

27. Coated sustained release tablet of claim 26, wherein the tablet contains by weight 4.8% mizolastine, 12% hydrogenated castor oil, 60% lactose and 9.6% L-tartaric acid.

28. Coated sustained release tablet of claim 27, wherein the tablet further contains 9.6% microcrystalline cellulose.--

#### R E M A R K S

Applicants disagree with the Examiner's rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Conte (U.S. 5,682,583). However, in order to expedite the allowance of this application, applicants have cancelled claims 1-23 without prejudice or disclaimer.

Applicants have taken this opportunity to add four dependent claims depending directly or indirectly from allowed claim 24. New dependent claim 25 is based on the specification at page 2, line 28, to page 3, line 2, as well as page 3, lines 15-16. New dependent claim 26 is based on the specification at page 3, lines 20-25. New dependent claims 27 and 28 are based on the example which appears at page 4, line 10 et seq.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance and an early Notice of Allowance is respectfully solicited.